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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,449	11/17/2003	Ruben Laguens	42597-193226	9366

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EXAMINER	
KAUSHAL, SUMESH	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,449	LAGUENS ET AL.	
	Examiner	Art Unit	
	Sumesh Kaushal Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-97* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 3 and 5-9, drawn to method for inducing arteriogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

II. Claims 4, 10-18, drawn to method for inducing cardiomyogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

III. Claim 1, 33 drawn to method for inducing lymphangiogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

IV. Claim 1, 33 drawn to method for inducing vasculogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

V. Claim 81-86 drawn to a kit comprising polynucleotide encoding SEQ ID NO:1, classified in class 536, subclass 23.1.

VI. Claims 87-89, drawn to method for inducing arteriogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

VII. Claim 87-89 and 95 drawn to method for inducing lymphangiogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

VIII. Claim 87-89 and 95 drawn to method for inducing vasculogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

IX. Claims 87-89, 90-92 and 95 drawn to method for inducing cardiomyogenesis by administering a polynucleotide that encodes VEGF, classified in class 514, subclass 44.

X. Claim 93-94 and 96-97 drawn to a kit comprising polypeptide encoding SEQ ID NO:1, classified in class 530, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VI-IX are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of group I-V relates to the polynucleotide sequences whereas inventions of group VI-X relates to the use of polypeptides. Polypeptides and polynucleotide are structurally and functionally distinct substance, wherein each has different modes of operation, different functions, or different effects. Thus these inventions are distinct and are of separate uses, wherein one can not substitute another.

Inventions I-IV and VI-IX are directed to related inventions. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the scope of arteriogenesis, cardiomyogenesis, lymphangiogenesis and vasculogenesis are mutually exclusive because each involves different structure and physiologically distinct process. For example, the process of cardiomyogenesis involves heart muscle cells whereas lymphangiogenesis involves lymph nodes, which have a materially different design, mode of operation, function, or effect. Thus these inventions are distinct and are of separate uses.

Inventions I-IV, VI-IX and V and X respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case besides gene therapy the polynucleotides could be used to make recombinant proteins. Similarly besides the protein the therapy the protein in the context could also be use to make antibodies against the protein. thus these inventions are distinct are of separate uses.

Claim 1-2, 19-80 link(s) inventions I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-2, 19-27. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper

1. This application contains claims directed to the following patentably distinct species: cardiomyocytes, skeletal cells and skeletal muscle cells. The species are independent or distinct because these cell are morphologically distinct population of cells having different physiological functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 16 is generic.

2. This application contains claims directed to the following patentably distinct species: type I and type II. The species are independent or distinct because these cell are morphologically distinct population of cells having different physiological functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic.

3. This application contains claims directed to the following patentably distinct species: striated, smooth, or myoepithelial cell. The species are independent or distinct because these cell are morphologically distinct population of cells having different physiological functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15 is generic.

4. This application contains claims directed to the following patentably distinct species: vascular smooth muscle cell and non-vascular smooth muscle cell. The

species are independent or distinct because these cell are morphologically distinct population of cells having different physiological functions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 18 is generic.

5. This application contains claims directed to the following patentably distinct species: myocardial infarction, myocardial ischemia, dilated cardiomyopathy, or hypertrophic cardiomyopathy. The species are independent or distinct because each disease have distinct etiology.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 34 is generic.

6. This application contains claims directed to the following patentably distinct species: parenteral, sublingual, inhalatory, oral or rectal route. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 37 generic.

7. This application contains claims directed to the following patentably distinct species: intravascular, intracelomic, intramuscular, subcutaneous, intraspinal, topical or intracardiac administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 39 generic.

8. This application contains claims directed to the following patentably distinct species: intravenous or intra-arterial. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 40 generic.

9. This application contains claims directed to the following patentably distinct species: intracoronary, intra-aortic, intrafemoral, intrapopliteal, intrapedialis, intra-posterior tibialis, intracarotideal or intraradialis administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 41 generic.

10. This application contains claims directed to the following patentably distinct species: intrapericardial, intraperitoneal, intra-amniotic sac or intrapleural administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 42 generic.

11. This application contains claims directed to the following patentably distinct species: intramyocardial or intra-peripheral muscle administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 43 generic.

12. This application contains claims directed to the following patentably distinct species: transepicardial or transendocardial administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 44 generic.

13. This application contains claims directed to the following patentably distinct species: periadventitial, perivascular, epicardial, epidermal, transdermal, ophthalmic or mucous absorption administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 45 generic.

14. This application contains claims directed to the following patentably distinct species: conjunctival, nasopharyngeal, bucopharyngeal, laryngopharyngeal, vaginal, colonic, urethral or vesicle mucosum. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 46 generic.

15. This application contains claims directed to the following patentably distinct species: yugalis, gingivoyugalis or gingivolabialis mucosum. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 47 generic.

16. This application contains claims directed to the following patentably distinct species: intra-atrial or intraventricular administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 48 generic.

17. This application contains claims directed to the following patentably distinct species: is intra-left atria administration or intra-right atria administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 49 generic.

18. This application contains claims directed to the following patentably distinct species: intra-left ventricle administration or intra-right ventricle administration. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 50 generic.

19. This application contains claims directed to the following patentably distinct species: intramyocardial-transepicardial injection under direct visualization, or intramyocardial-transendocardial injection under fluoroscopic guidance . The species are independent or distinct because these routes involve distinct methods that require different modes of operation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 51 generic.

20. This application contains claims directed to the following patentably distinct species: injection perpendicular to the plane of the area of injection, injection parallel to the plane of the area of injection, injection is between about 30.degree. and about 90.degree or injections that are homogeneously or heterogeneously distributed in the area of injection (see claims 52-55). The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

21. This application contains claims directed to the following patentably distinct species: smooth muscle cell, skeletal muscle cell or cardiomyocyte. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 65 generic.

22. This application contains claims directed to the following patentably distinct species: myocardial tissue, skeletal tissue, cardiac tissue, muscle tissue (see claims 67-70). The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 65 generic.

23. This application contains claims directed to the following patentably distinct species: normoperfused tissue, ischemic tissue, myocardial tissue, hypoperfused tissue (see claims 74-80. The species are independent or distinct because these routes involve physiologically distinct locations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 65 and 76 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants

or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

In addition in order to be perfectly clear, the following Inventions within the particular Groups are NOT species elections. These are independent and distinct Inventions for the reasons given above and a further election of a single Invention from the elected Group is required.

With regard to Groups V the independent and distinct Inventions are as follows:

a label or instructions indicating a use for polynucleotide to induce

1. arteriogenesis
2. lymphangiogenesis
3. vasculogenesis,
4. cardiomyogenesis
5. mitosis
6. proliferation of a smooth muscle cell
7. proliferation of a skeletal muscle cell
8. proliferation of a cardiomyocyte.

With regard to Groups X the independent and distinct Inventions are as follows:

a label or instructions indicating a use for the polypeptide to induce

1. arteriogenesis
2. lymphangiogenesis
3. vasculogenesis
4. cardiomyogenesis

5. mitosis
6. proliferation of a cardiomyocyte.

With regard to the different Inventions above, the burden of search exists because a different search is required for each separate invention. Furthermore the instruction in each context is distinct from each other as each use have different modes of operation, functions and effects, which need to be separately reviewed especially in view of label instructions. Since the review of this information would be different for each invention it would be burdensome.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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